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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,627	12/14/2001	William M. Switzer	14114.0331US2	5188

7590

12/16/2003

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,627

Applicant(s)

SWITZER ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This action is in response Amendment B, filed 10/3/03.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 11 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for said claims. The specification does not provide a repeatable method for obtaining the inventive spumavirus and it does not appear to be readily available material. Deposit of virus would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit statement on specification page 18, lines 18 and 19 , does not indicate the extent of public availability.

Applicant argues that the specification indicates the deposit on page 18, lines 18- and 19 is according to the Budapest Treaty and further states that all restrictions imposed by the depositor will be irrevocably removed by the depositor upon granting of a patent.

This argument is found persuasive. The second part of the argument fulfills the deposit requirements of 37 CFR 1.808.

Rejections Maintained

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Claims 3- 6 and 7- 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a virus with an insert and a method of killing dividing cells, *in vivo* and *in vitro* with the virus of the invention, as well as inhibiting tumor formation or growth.

Applicant argues that applicant is not required to teach what is well known in the art, that the examiner is confused about the terminology of dividing cells and disease, that the examiner alleges that the specification does not teach how to make the viruses, that the specification does not need to teach molecular biology, that Heneine teaches information on the virus, that Schenk does not in fact teach complex and unpredictable, but complex and can be manipulated, and that the specification does disclose that the virus can be used to treat cancer.

The arguments have been fully considered and found persuasive in part.

The examiner is not indicating that the specification must teach molecular biology, routine lab procedures, or manipulation of clones to insert heterologous DNA. The virus of Schenk is a replication competent mutant not a wild type spumavirus and Schenk does not teach that heterologous DNA can be expressed from the clone for purposes of gene therapy. The virus of the instant specification has been partially sequenced. No infectious clones have been made. Applicant has not demonstrated that

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an infectious clone will have the same properties of the isolate. Without an infectious clone, no heterologous DNA can be expressed.

The virus as indicated in Heneine is not used to express heterologous DNA or treat cancer. The main finding is that Spumaviruses do not kill the host, they come from non-human primates, and the virus is apparently not transmissible to others.

Applicant argues that the specification discloses the use to treat cancer (page 17). Applicant's response indicates it is permissible to administer the virus to a host to treat cancer. The specification does not teach what tumors can be successfully treated with virus or what method is involved beyond "administering."

The prior art has not demonstrated any anti-tumor treatments or other treatments *in vivo* using a spumavirus. While the virus may kill dividing cells *in vitro*, there is no evidence to show that it will work *in vivo* as claimed.

Claims 3- 6 and 7- 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a virus with an insert and a method of killing dividing cells, *in vivo* and *in vitro* with the virus of the invention as well as inhibiting tumor formation or growth.

The burden of the written description requirement in this application of a SFVHu-6 with an insert and a method of killing dividing cells, *in vivo* and *in vitro* with the

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SFVHu-6 of the invention as well as inhibiting tumor formation or growth has not been met.

Applicants state that they have provided detailed nucleic acid sequence sequences, that the specification teaches that the virus can inhibit growth or formation of tumors, and that the Office has the burden of establishing why one of skill in the art would not recognize in the disclosure the claims.

The arguments have been fully considered and not found persuasive.

Applicant has provided only 3576 bases of viral sequence. The genomes are known to be over 11Kb. As disclosed on page 10 it is from HSV-Hu6. Without an entire sequence and an infectious clone, one of skill in the art would not know if the sequence provided comprises an infectious clone. Without such a clone, no heterologous DNA can be expressed from a virus. Without examples showing that the virus with or without a heterologous insert can prevent the formation of tumors, one of skill in the art would not see treatment.

The rejection is maintained.

Conclusion

No claim is allowed.

This application contains claims to sequences drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Sequence 1 and the deposited virus are free of the prior art.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

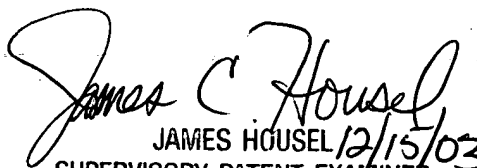
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Myron G. Hill
Patent Examiner
December 14, 2003


JAMES HOUSEL 12/15/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600